NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff, vs. MYLAN PHARMACEUTICALS CORPORATION, INC., et al., Defendants.	Civil Action No.: 08-5042 (PGS) **OPINION**

This is a patent infringement case. Plaintiff Novartis Pharmaceutical Corporation (Novartis) holds U.S. Patent No. 5,354,772 ('772 Patent), which claims racemic erythro fluvastatin sodium, the active ingredient in Novartis's anticholesterol drug Lescol®. Mylan Pharmaceuticals Inc. and Mylan Inc. (collectively Mylan) filed an Abbreviated New Drug Application (ANDA), which would permit Mylan to make a generic copy of Lescol®. Mylan asserts that its ANDA does not infringe on the '772 Patent because it is unenforceable under the doctrines of prosecution laches and patent misuse.

The parties are currently before the Court on two motions for summary judgment. Novartis moves for summary judgment to dispose of the affirmative defenses of prosecution laches and patent misuse. Mylan cross-moves for summary judgment on the basis of the affirmative defense of prosecution laches.[1]

[1] Mylan indicated in its motion that it did not move for summary judgment on the defense of patent misuse because "[t]hat defense would be mooted if the Court granted the instant motion."

I. BACKGROUND

Novartis holds New Drug Application (NDA) No. 20-261 for Lescol®. Mylan seeks to market a generic copy of Lescol®, and on June 3, 2008, filed an ANDA with the U.S. Food and Drug Administration (FDA) for that purpose. Mylan's ANDA includes a certification challenging the enforceability of the '772 Patent under the doctrine of prosecution laches. In October 2008, Novartis sued Mylan for infringement of the '772 Patent, and about a year later, Mylan stipulated to infringement of the '772 Patent if the '772 Patent is found to be enforceable.

A. Novartis's Development of Lescol®

In 1979, Dr. Faizulla G. Kathawala, the director of the anticholesterol drug program at Sandoz Pharmaceuticals Corporation,[2] led a team of scientists to discover and synthesize compounds she hoped would be effective statins for inhibiting cholesterol biosynthesis. On March 30, 1983, Novartis first synthesized fluvastatin sodium. In July 1983, fluvastatin sodium was internally promoted to "IW" status, which is an acronym for a German term, meaning "interesting substance." In June 1984, as part of its critical time path, Novartis planned to request an "Investigational New Drug Exemption" (IND) from the FDA on or about March 1986. In November 1984, fluvastatin sodium was promoted again, this time to "AW" status, which means "actual substance." As planned, Novartis submitted its IND to the FDA on September 9, 1986. Thereafter, on March 31, 1992, it filed its NDA. The FDA approved Novartis's NDA for Lescol® on December 31, 1993, thereby giving Novartis the ability to commercially market Lescol®.

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[2] Sandoz Pharmaceutical Corporation changed its name to Novartis on December 23, 1996, and Novartis now owns the relevant patents. For simplification purposes, any references to Sandoz and/or Novartis will simply be referred to as Novartis.

B. Novartis's Prosecution of Claims Related to Fluvastatin Sodium

The following five patent applications stemming from Dr. Kathawala's research are relevant to the prosecution history of the '772 Patent: (1) 06/443,668 ('668 Application); (2) 06/548,850 ('850 Application); (3) 06/707,854 ('854 Application), which issued as U.S. Patent No. 4,739,073 ('073 Patent); (4) 06/772,228 ('288 Application); and (5) 08/157,595 ('595 Application), which issued as the '772 Patent. In the patent practice, all of those applications are related or called continuing applications. Three types of continuing applications are relevant to this case: (1) a continuation, (2) a divisional, and (3) a continuation-in-part (CIP) Application.

Continuation applications and divisional applications are similar because they are both continuing applications based on the same disclosure made in an earlier application, but they differ in what they claim. "A continuation application claims the same invention claimed in an earlier application, although there may be some variation in the scope of the subject matter claimed. A divisional application, on the other hand, is one carved out of an earlier application that disclosed and claimed more than one independent invention."[3] Another type of continuing application is a CIP Application, which contains not only a portion of or all of the disclosure previously made in an earlier application but also new matter that was not included in the earlier application. Ultimately, regardless of what term is used to describe a continuation application, the continuation application gains the benefit of the filing date of the earlier application for the common subject matter. Novartis's patent attorney Melvyn Kassenoff prosecuted each of the aforementioned continuing applications in such a manner. A review of the evidence presented in this case did not reveal any third party activity with regard to the claims made by Novartis in the five patent applications.

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[3] Robert Harmon, *Patents and the Federal Circuit* 1137 (9th ed. 2009).

1. The '668 Application

The first application for the '772 Patent – the '668 Application – was filed by Novartis on November 22, 1982. It did not disclose racemic erythro fluvastatin sodium because the compound fluvastatin had not yet been identified. On October 18, 1983, Kassenoff informed the United States Patent and Trademark Office (PTO) that he intended to abandon the '688 Application and refile it as a CIP Application.

2. The '850 Application

The '850 Application was filed as a CIP Application of the '668 Application on November 4, 1983. The '850 Application contained 20 claims and included new information related to the synthesis and testing of additional compounds, including racemic erythro fluvastatin sodium. In May 1984, the PTO issued a non-final office action in which it allowed claims 3-8 (including claim 7, which covered racemic erythro fluvastatin sodium), 11-12, and 18-19, but rejected claims 1-2, 9-10, 13-17, and 20. The parties agree that while claim 7 of the '850 Application covers racemic erythro fluvastatin sodium, the '850 Application contained no claims specific to erythro fluvastatin sodium.[4]

In an October 26, 1984, telephonic interview, the PTO issued a restriction requirement. Such a requirement issues when the examiner determines that there is more than one invention claimed in the application and requires that the applicant choose one invention to prosecute. Kassenoff was required to choose between prosecution of either claims 1-19 drawn to final product, compositions, and method, or prosecution of claim 20 drawn to intermediate compounds. Kassenoff prosecuted claims 1-19.

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[4] Mylan disputes that this fact is material, apparently asserting that it is irrelevant whether the '850 Application contained claims specific to erythro fluvastatin sodium because claim 7 of the '850 Application covered racemic erythro fluvastatin sodium; thus, Novartis could have accepted a claim covering racemic erythro fluvastatin sodium at that time.

On December 5, 1984, the PTO allowed claims 1-19 and cancelled claim 20. Despite the PTO's allowance, Novartis did not pay the issue fee to the PTO for claims 1-19 by the deadline date of March 5, 1985; hence, a patent never issued. Rather, as described below, Kassenoff filed the '854 Application on March 4, 1985, and subsequently abandoned the '850 Application on April 26, 1985.

During the deposition of Kassenoff, he admitted that the '850 Application contained an allowable claim for fluvastatin sodium, but claims the abandonment was reasonable under the circumstances. First, Kassenoff explained that he chose not to pursue the genus claims and subgenus claims in different applications because he had been taught in the Patent Office Academy "not [to] divide up a subgeneric claim from a generic claim on it." As a result, "it was against [his] policy to take out generic claims and what would be subgeneric and species claims in two different applications." He explained that he "distinctly recall[ed] somebody dealing with the issue of double patenting and it was hemmed into me or banged into me one invention, one patent on it. That you did not divide up a subgeneric claim from a generic claim on it." Kassenoff also noted that "it would have required the filing of a terminal disclaimer, which would require the patents to be commonly assigned throughout. That is an invitation to disaster, because you don't know what's going to happen down the line." Nevertheless, Novartis has prosecuted patents with terminal disclaimers[5] in the past.

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[5] A terminal disclaimer is filed to avoid a double patenting situation. Robert F. Schwartz & Robert J. Goldman, *Patent Law and Practice* 35 n.88 (6th ed. 2008) (citation omitted). When a patentee "discovers that there might be a substantial question as to the validity of a patent or claim," the patentee can disclaim "an entire patent, or the entire term of a complete claim." *Id.* "The terminal portion of the term of a patent might be disclaimed if the patentee realizes that he or she has duplicate coverage in another patent. The terminal disclaimer would cause both patents to expire on the same day . . . ." *Id.*

Second, Kassenoff also stated that he was concerned with maintenance fees, testifying that by 1984-85, "we were already in the era of maintenance fees. If you take two patents, you have a double set of maintenance fees. And there is no reason to do that." Although he admitted that Novartis "could afford to pay th[e] issue fee" for the allowed claims in the '850 Application, he explained that "the record shows that [the issue fee] was not paid in order to file a continuation in part."

Third, Kassenoff expressed that "if you take out two patents it violates the KISS principle on it." KISS stands for "keep it simple, stupid." Kassenoff concedes that KISS is "not a principle of patent law," but asserts that "it's nevertheless a good policy."

3. The '854 Application

On March 4, 1985, Kassenoff filed the '854 Application as a CIP Application of the '850 Application. The '854 Application contained the same 20 claims as were in the '850 Application. On July 23, 1986, the PTO issued a restriction requirement identical to the one issued in the '850 Application. In issuing the restriction, the PTO noted that on November 22, 1985, Kassenoff had provisionally elected to prosecute claim 20. Based on Kassenoff's election, the PTO withdrew claims 1-19 from consideration.

Shortly thereafter, Kassenoff filed a reply with the PTO, in which he redesignated the '854 Application as a divisional of the '850 Application, elected to prosecute the intermediate compounds in the '854 Application, and elected to prosecute the final product compositions in the '288 Application. Kassenoff also added new claims 21-39 and cancelled claims 1-19. On April 19, 1988, the '854 Application issued as the '073 Patent, which disclosed racemic erythro fluvastatin sodium to the public and also made publicly available the '668, '850, and '854 Applications. Mylan asserts that the facts related to the prosecution of the '854 Application are immaterial and that the '854

Application is part of the delay in permitting the allowed claims to issue because Novartis put all the claims from the '850 Application into the '854 Application to keep the allowed fluvastatin sodium claims together.

4. The '288 Application

On April 11, 1985, Kassenoff filed the '288 Application as a CIP Application of the '854 Application. Claims 1, 2, and 19-21 of the '288 Application sought to replace the ester group of the '850 Application with a broader group of esters, including fluvastatin ester derivatives having the "physiologically acceptable and hydrolyzable ester group." Again, the PTO issued a restriction requirement. Kassenoff indicated to the PTO that while he wished to elect claims 1-26, he would traverse, or contest, the PTO's restriction requirement.

At the time of filing the '854 Application, the broader claims had been included in European patent application, No. EP 114,027 (European Patent), which had been filed by a European Novartis entity on November 21, 1983. Prior to the April 1985 filing of the '288 Application, patents issued in both Spain and Greece with claims disclosing physiologically acceptable and hydrolyzable esters. Kassenoff advised the PTO of Spanish Patent 527,428/1 (Spanish Patent) on November 27, 1985. He further apprised the PTO on December 2, 1985, that he believed that the Spanish Patent was the counterpart of the grandparent '850 Application and had been granted in January 1985, but that it had not been published until August 1, 1985, which was after the filing of the '854 Application. On January 21, 1986, Kassenoff filed an Information Disclosure Statement (IDS), about prior art, wherein he cited eleven U.S. patents, three foreign patent documents, and three non-patent literature documents.

On January 24, 1986, in a non-final office action, the PTO rejected claims 1-2, and 19-21 as anticipated by the European Patent, which was published on July 25, 1984. The PTO also

objected to claims 3-18 and 22-26, but stated that those claims would be allowable if rewritten in independent form. In addition, the PTO examiners restricted claims 1-25 drawn to final products, composition, and methods, from the invention of claim 27 drawn to intermediate compounds. Finally, the PTO advised Kassenoff of the holding in *Ex Parte Hull*, 191 U.S.P.Q. 157 (B.P.A.I. 1975), for any subsequent patent applications that might be abandoned upon allowance.[6]

On April 21, 1986, in response to the PTO office action of January 24, 1986, Kassenoff argued against the anticipated rejection, asserting that the rejection was

> improper because the European published patent application is not a reference against this application because (I) it is applicant's own publication and (ii) its effective date as a reference, its date of publication (July 25, 1984), is less than one year prior to the filing date of this application (April 11, 1985).

Kassenoff distinguished *Ex parte Hull*, by arguing that

> [i]n the second complete paragraph of page 4 of the office action, applicant's attention was directed to *Ex parte Hull*, 191 U.S.P.Q. 157. However, even if this application were to be refiled as a continuation-in-part subsequent to its allowance in order to include additional subject matter (which is not presently contemplated but is always a possibility), there would be several differences between the fact situation in *Hull* and the instant one: (1) The involved application in *Hull* was the sixth one in the chain rather than the fifth one. (2) Each of the previous five applications in *Hull* was allowed rather than only two (application ['850] and this one). (3) Hull kept refiling his application as continuations-in-part in order to preclude the publication of his invention whereas most of the subject matter of this application had already been published; see, for example, European Published Patent Application 114,027, the reference upon which the 35 USC 102(a) rejection is based.

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[6] *Ex parte Hull* is a case often cited by the PTO to warn that the successive filing of continuation applications, without substantive amendments to advance prosecution of the invention, could constitute equitable laches and result in the loss of patent rights. *See In re Bogese*, 303 F.3d 1362, 1364-65 (3d Cir. 2002).

Kassenoff also addressed the issuance of the Spanish Patent as follows:

> In accordance with the request set forth in the last paragraph of the office action, a copy of Spanish Patent 527,428/1, the Spanish [P]atent . . . is appended. According to our Spanish agents, while the Spanish [P]atent was granted on January 21, 1985, a notice of the grant was not published in the bulletin of the Spanish Patent Office until August 1, 1985. It was on the latter date that the patent was made available to the public; however, the patent itself was not published. Since the Spanish [P]atent was granted on an application filed in Spain on November 21, 1983, which is more than one year prior to the filing date of this application, *i.e.*, April 11, 1985, which date is subsequent to January 21, 1985 but precedes August 1, 1985, the Examiner must determine whether, for purposes of 35 USC § 102(d), the effective date of the Spanish [P]atent is January 21, 1985 or August 1, 1985. If the former, Claims 1,2 and 19-21 as they currently stand may be rejectable under 35 USC § 102(d). In this connection, the Examiner may wish to consider M.P.E.P. 706.03(d) and 901.05(b) and the decisions and Journal of the Patent Office Society articles cited therein.

Novartis also canceled claim 27 and added claim 28, dependent on rejected claim 19.

On July 23, 1986, the PTO issued a non-final office action, rejecting claims 1-2 and 19-21 as unpatentable under 35 U.S.C. § 103 based on 35 U.S.C. § 102(d) because the Spanish Patent was granted on January 21, 1985. The PTO also objected to claims 3-18, 22-26, and 28. Kassenoff filed a Request for Reconsideration on October 22, 1986, in which he traversed the rejection of the claims based on the Spanish Patent, arguing that 35 U.S.C. § 102(d) is not a prior art provision, and therefore could not serve as the proper basis for a rejection. On February 24, 1987, the PTO maintained its position.

As before, Kassenoff filed a Request for Reconsideration maintaining his assertion that the Spanish Patent was "secret" and that it could not be prior art. In his request, Kassenoff also brought the Examiners' attention to the issuance of Greek Patent 79,042, (Greek Patent) explaining that "[t]he undersigned would like to apologize to the Examiner for not apprising him of Greek Patent

79,042 at an earlier time. However, it was only subsequent to the issuance of the Final Rejection that the undersigned learned that Greek Patent 79,042 was granted on October 2, 1984." Kassenoff never re-wrote claims 3-18, 22-26, or 28 during the pendency of the '288 Application.

When the PTO maintained their rejections, Kassenoff appealed the rejection to the Board of Patent Appeals and Interferences (BPAI). Kassenoff filed an Appellate Brief with the BPAI on August 21, 1987. The PTO issued an Examiner's Answer on December 23, 1987, rejecting claims 1-2 under 35 U.S.C. § 103 over the Spanish Patent and claims 1-2 and 19-21 under 35 U.S.C. § 102(d) as barred by the Greek Patent. The rejection under 35 U.S.C. § 102(d) was a new ground of rejection, which first occurred during the appeal.

On January 22, 1988, Kassenoff continued the appeal process before the BPAI by requesting oral argument. Briefing in the BPAI appeal was completed on February 8, 1988, with the filing of Novartis's Reply Brief. Novartis's Reply Brief argued that

> (1) the Greek Patent 79,024 cannot form the basis for a 35 U.S.C. § 102(d) rejection because there is no conclusive evidence that its effective date as a reference precedes April 11, 1985, the filing date of this application; (2) Claims 1-2, and 19-21 are not rejectable under 35 U.S.C. § 102(d) over Greek Patent 79,042 because none of the compounds, pharmaceutical compositions and methods of use that they embrace was patented in Greece.

On February 27, 1990, two years after Novartis filed its Reply Brief, the BPAI remanded the '288 Application to the PTO Examiner "to afford the Examiner and the appellant the opportunity to make of record objective evidence as to the applicable law of Spain and Greece to establish the effective dates of the Spanish and Greek patents for the purposes of 35 U.S.C. § 102(d)."

On March 8, 1990, Kassenoff filed a Communication, which informed the PTO that the Spanish and Greek patents were enforceable as of their respective dates of grant. The Spanish Patent was enforceable as of January 21, 1985, although it was not available to the public until August 1,

1985. The Greek patent was enforceable as of October 2, 1984, although it may not have been publicly available until as late as June 17, 1985. However, Kassenoff asserted that the grant dates were not the effective dates for the purpose of a 35 U.S.C. § 102(d) analysis. He echoed that argument in a March 13, 1990, telephone interview with PTO examiners.

The PTO issued a Supplemental Examiner's Answer on April 19, 1990, maintaining that a secret patent can bar a patent under 35 U.S.C. § 102(d). The next month, on May 18, 1990, Kassenoff filed a Supplemental Reply Brief objecting. Thereafter, on August 17, 1990, the BPAI remanded the '288 Application back to the PTO for consideration of Novartis's Supplemental Reply Brief. The PTO issued a second Supplemental Examiner's Answer on August 24, 1990, arguing that a secret patent can create a § 102(d) bar pursuant to *Ex parte Gruschwitz*, 138 U.S.P.Q. 505 (B.P.A.I. 1961). Again, Kassenoff disagreed with the PTO's interpretation and filed another Supplemental Reply Brief on September 13, 1990.

A third Supplemental Examiner's Answer was issued by the PTO on October 9, 1990, in which the PTO Examiner disputed Kassenoff's interpretation of *Ex parte Gruschwitz*. Approximately six months later, on April 9, 1991, the BPAI affirmed the PTO's rejections. Kassenoff filed a Request for Reconsideration on April 22, 1991, to correct clerical and typographical errors in the file. Kassenoff's request was granted on May 16, 1991. On June 7, 1991, Kassenoff appealed to the Federal Circuit.

On June 18, 1991, Fred E. McKelvey, Solicitor for the PTO, requested that Kassenoff further investigate the filing date for the Spanish Patent application. Solicitor McKelvey wrote as follows:

> It would be appropriate for [Novartis] to further investigate the filing date of the application which matured into the Spanish Patent. If the patent is not prior art, there is no reason to proceed before the Federal Circuit on the issue of whether the Spanish Patent renders the claims on appeal unpatentable . . . Please let me know what your

investigation reveals.

Kassenoff addressed Solicitor McKelvey's request in his Appellate Brief to the Federal Circuit on August 16, 1991. Kassenoff maintained that the Spanish and Greek Patents were not prior art and could not bar the patentability of Novartis's claims under 35 U.S.C. §§ 102(d) or 103 for the following two reasons: (1) the Spanish and Greek Patents were not made public until after the filing date of the '288 Application; and (2) the Greek Patent does not contain claims that validly cover any of the compounds, pharmaceutical compositions, and methods of use of claims 1-2, and 19-21 of the '288 Application. Shortly thereafter, in letters dated September 3, 1991, and September 26, 1991, the Assistant Commissioner of External Affairs for the PTO, Michael K. Kirk, sought guidance from the Greek Industrial Property Organization as to the patent laws in effect at the relevant times.

The PTO submitted its brief to the Federal Circuit on October 21, 1991, requesting that the matter be remanded to the BPAI for consideration of additional evidence. On November 4, 1991, Novartis moved for a 14-day extension of time to file his Appellate Reply Brief, but the next day, the Federal Circuit remanded the '288 Application back to the BPAI. On November 12, 1991, Solicitor McKelvey set a two month period for Novartis to submit additional evidence to the BPAI. Following a one month extension of time, on March 11, 1992, Kassenoff filed a Communication and two Declarations under 37 C.F.R. 1.132 in support of his Appellate Brief to supplement a Communication, which was filed February 11, 1992.

On July 17, 1992, on remand to the BPAI, a five-member panel the BPAI reaffirmed the PTO Examiner's rejection of claims 1-2 of the '288 Application over the Spanish Patent and determined that claims 1-2 and 19-21 of the '288 Application were unpatentable under 35 U.S.C. § 102(d) and/or § 103 over the Greek Patent. Kassenoff requested reconsideration of the BPAI decision to correct typographical errors and to ensure that one of the declarations was properly considered. The Request

also stated the following:

> [T]he fact that appellant opted not to request reconsideration of the Board's holding affirming the rejections on appeal does not mean that the appellant concurs in the rejections. Rather, appellant refrained from requesting reconsideration of the Board's holding in order not to delay the ultimate resolution of the involved issues by the United States Court of Appeals for the Federal Circuit.

The BPAI granted the request on September 14, 1992, and corrected two typographical errors and referred the declarations submitted by Novartis. It also noted Kassenoff's interest in judicial expedience. On November 23, 1992, Kassenoff appealed the BPAI's July 17, 1992 and September 14, 1992, decisions to the Federal Circuit. Ultimately, over a year later, on November 9, 1993, the Federal Circuit affirmed the BPAI's rejection of the broadened ester group claims of the '288 Application.

5. The '595 Application

The '595 Application was filed on November 24, 1993, as a CIP Application of the '288 Application. Concurrent with the filing of the '595 Application, Kassenoff filed an amendment excising the rejected broadened ester group from the claims and adding new claims 28-37. The '595 Application contained claim 29, which was specific to the sodium salt of fluvastatin in racemic erythro form. An Examiner's Statement of Reasons for Allowance was issued by the PTO on April 14, 1994, which allowed the claims of the '595 Application. The '595 Application issued as the '772 Patent on October 11, 1994.

II. STANDARD OF REVIEW

Summary judgment is appropriate under Rule 56© of the Federal Rules of Civil Procedure "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986) (internal quotations omitted). A factual dispute is genuine if a reasonable jury could return a verdict for the non-movant, and it is material if, under the substantive law, it would affect the outcome of the suit. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). "In considering a motion for summary judgment, a district court may not make credibility determinations or engage in any weighing of the evidence; instead, the non-moving party's evidence 'is to be believed and all justifiable inferences are to be drawn in his favor.'" *Marino v. Indus. Crating Co.*, 358 F.3d 241, 247 (3d Cir. 2004) (quoting *Anderson*, 477 U.S. at 255).

Once the moving party has satisfied its initial burden, the party opposing the motion must establish that a genuine issue as to a material fact exists. *Jersey Cent. Power & Light Co. v. Lacey*, 772 F.2d 1103, 1109 (3d Cir. 1985). The party opposing the motion for summary judgment cannot rest on mere allegations. *Anderson*, 477 U.S. at 248. "[U]nsupported allegations" are insufficient to defeat summary judgment. *Schoch v. First Fidelity Bancorp.*, 912 F.2d 654, 657 (3d Cir. 1990). Moreover, only disputes over facts that might affect the outcome of the lawsuit under governing law will preclude the entry of summary judgement. *Anderson*, 477 U.S. at 247-48. If a court determines, "after drawing all inferences in favor of [the non-moving party], and making all credibility determinations in his favor – that no reasonable jury could find for him, summary judgment is appropriate." *Alevras v. Tacopina*, 226 Fed. Appx. 222, 227 (3d Cir. 2007).

III. DISCUSSION

A. Prosecution Laches

"The doctrine of prosecution laches is an equitable defense." *Symbol Techs., Inc. v. Lemelson Med.*, 277 F.3d 1361, 1366 (Fed. Cir. 2002) ("*Symbol Techs. I*"). A defense of prosecution laches renders "a patent unenforceable if there has been an unreasonable and unexplained delay in the prosecution even though the applicant complied with pertinent statutes and rules." *MOSAID Techs. Inc. v. Samsung Elecs. Co.*, 362 F. Supp. 2d 526, 551 (D.N.J. 2005) (internal quotation marks and citation omitted). Stated another way, "[t]he doctrine 'may render a patent unenforceable when it has issued only after an unreasonable and unexplained delay in prosecution' that constitutes an egregious misuse of the statutory patent system under the totality of the circumstances." *Cancer Research Tech. Ltd. v. Barr Labs., Inc.*, 625 F.3d 724, 2010 U.S. App. LEXIS 23214, *10 (Fed. Cir. 2010) (quoting *Symbol Techs. Inc. v. Lemelson Med.*, 422 F.3d 1378 (Fed. Cir. 2005) ("*Symbol Techs. II*")).

Novartis argues that Mylan's prosecution laches defense fails as a matter of law because the defense requires a showing that intervening rights of others to the patented subject matter were prejudiced by the alleged delay. Novartis contends that Mylan has no proof that it or a third party has or had intervening rights to the subject matter. Alternatively, Novartis argues that it did not engage in any unreasonable and unexplained delay when prosecuting the '772 Patent. Novartis maintains that the defense is sparingly used and that the prosecution history of the '772 Patent is "a far cry" from the unreasonable and unexplained delay present where courts found the defense applicable.

Mylan contends that Novartis is not entitled to summary judgment of no prosecution laches because intervening rights is not an element of a prosecution laches defense. Mylan also asserts that

Novartis's filing of a broadened CIP Application is not a safe harbor that would negate its prosecution laches defense. Further, Mylan posits that Novartis's prosecution of the '772 Patent was unreasonable because Novartis delayed accepting the allowed fluvastatin claims for ten years, thereby having the effect of extending the term of Novartis's patent from 2002 to 2011, which in turn caused the allowable claims to issue in close proximity with the commercial availability of Lescol®.

During the pendency of the instant motions, *Cancer Research Technology Limited v. Barr Laboratories, Inc.*, 679 F. Supp. 2d 560 (D. Del. 2010) – one of the few cases in which prosecution laches has been found – was appealed to the Federal Circuit. *Cancer Research Technologies* squarely presented the issue of whether intervening rights is required for a finding of prosecution laches. *Cancer Research Tech.*, 2010 U.S. App. LEXIS 23214.[7] In a split decision, the majority held that "prosecution laches' requirement of an unreasonable and unexplained delay includes a finding of prejudice, as does any laches defense."[8] *Id.* at *12-13 (citing *A.C. Aukerman Co. v. R.L.*

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[7] *Cancer Research Technology* was decided on November 9, 2010; the same day that the Court heard oral argument from the parties in this matter. The Court allowed the parties to submit letters to the Court regarding the impact of the *Cancer Research Technology* decision on the instant motion. Mylan requested that the Court refrain from ruling on the prosecution laches defense until trial due to the possibility that the Federal Circuit may hold a rehearing *en banc*. While there has been a request for a rehearing *en banc* in *Cancer Research Technology*, the Federal Circuit has as of yet to rule on whether such a rehearing will take place. With trial in this case set for January 24, 2011, this Court can no longer delay ruling on Mylan's prosecution laches defense. Further, the parties apprised the Court that the thirty-month stay in this ANDA case expires on March 2, 2011. Therefore, should the Federal Circuit decide to readdress the issue of intervening rights in a rehearing *en banc*, it is not likely that it will rule on the issue before the stay expires.

[8] Circuit Judge Prost disagreed with majority's conclusion that precedent compels a showing of intervening rights. *Id.* at *29-30 (Prost, C.J., dissenting). The dissent also contended that there was "*no* basis, in the relevant case law or otherwise," to support "the majority's further temporal limitation that the prejudice exists during the period of delay." *Id.* at *30. He posited that "I would hold that the more generalized harm associated with the improper extension of the patent monopoly, including the accompanying market uncertainty and denial to the public of free use of the invention, is sufficient prejudice to justify the use of an equitable defense." *Id.* at *35.

Chaides Constr. Co., 960 F.2d 1020, 1028 (Fed. Cir. 1992) ("Two elements underlie the defense of laches: (a) the patentee's delay in bringing suit was unreasonable and inexcusable, and (b) the alleged infringer suffered material prejudice attributable to the delay.")). For a court to find prejudice, the "accussed infringer must show evidence of intervening rights, *i.e.*, that either the accused infringer or others invested in, worked on, or used the claimed technology during the period of delay." *Id.* at *13.

Since the Federal Circuit has held that a finding of unreasonable and unexplained delay requires a finding of prejudice – "that either the accused infringer or others invested in, worked on, or used the claimed technology during the period of delay" – the Court concludes Mylan's defense of prosecution laches is dismissed because no such proof is presented. Mylan "has conceded it has no evidence of its own, *private* intervening rights," but asserts that it "has adduced ample evidence of public intervening rights arising from harm to generic competition due to Novartis' deliberate delay in permitting issuance of the Allowed Fluvastatin Claims." Mylan relies on its economic expert, Philip Nelson, but his opinion is vague and not compelling.[9] Nelson's report does not set forth specific evidence that during the period of alleged delay, other entities invested in, worked on, or used technology claimed in the '772 Patent. Certainly, there is no genuine issue of material fact, which exists as to whether any public intervening rights existed during the period of Novartis's alleged delay! Hence, the Court is not required to make any decision based upon speculative evidence of public intervening rights.

Assuming that *Cancer Research Technologies* is reversed, the result would not change. The

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[9] In regards to Nelson's report, the Court notes that Mylan failed to utilize citations to point the Court to locations in the report that contained evidence of the existence of public intervening rights.

doctrine of prosecution laches is one that "should be used sparingly" and "applied only in egregious cases of misuse of the statutory patent system." *Symbol Techs. II*, 422 F.3d at 1385. Further, the existence of prosecution laches is a discretionary decision of the Court. *Id.* Moreover, the Federal Circuit has advised that "[t]here are legitimate grounds for refiling a patent application which should not normally be grounds for a holding of prosecution laches." *Id.* For example the following filings and refilings of applications may be legitimate: (1) the filing of a divisional application in response to a restriction requirement, (2) refiling an application with rejected claims to present "evidence of unexpected advantages of an invention when that evidence may not have existed at the time of the original rejection," and (3) refiling an application "to add subject matter in order to attempt to support broader claims as the development of an invention progresses." *Id.*

To discern whether the equitable doctrine of laches could be triggered, absent intervening rights, the Court reviewed the totality of the circumstances surrounding the prosecution of the '772 Patent, including the prosecution history of all five patent applications at issue in this case and the overall delay in the issuance of a claim for racemic erythro fluvastatin sodium. *See id.* at 1386. The Federal Circuit has counseled that "refiling an application solely containing previously-allowed claims for the business purpose of delaying their issuance can be an abuse of the patent system." *Id.* (citation omitted). The PTO alerted Novartis about such abuse during the prosecution of the '288 Application by mentioning *Ex parte Hull*. However, the fact the PTO allowed '595 Application to issue as the '772 Patent makes clear that the PTO found *Ex parte Hull* inapplicable to Novartis's prosecution of the five patent applications. Upon the Court's own examination of the record, the Court agrees that *Ex parte Hull* does not apply.

Although Kassenoff filed CIP Applications that contained claims abandoned in prior applications, there was no unjustifiable delay. Kassenoff actively prosecuted the five patent

applications, filing each CIP Application within a month of abandoning the prior applications. The greatest delay in the prosecution of the '772 Patent was obviously the prosecution of the '288 Application, which constituted more than eight years of the ten year delay in the issuance of a claim covering fluvastatin sodium. At first blush, eight years seems like a long period of time to prosecute a patent application, but not when considered in light of the procedural history of the '288 Application. The passage of time is attributable to the appeals to the BPAI and Federal Circuit. Such passage of time is not atypical when there is an appeal. *See Liberty Lincoln-Mercury, Inc. v. Ford Motor Co.*, No. 02-cv-4146(PGS). Further, much of the delay in the prosecution of the '288 Application is attributable to the PTO, the BPAI, and the Federal Circuit, not Kassenoff. Moreover, the Federal Circuit has stated that "the delay in the prosecution on any one particular application will surely not appear to merit relief by the courts in equity." *Symbol Techs. II*, 422 F.3d at 1385-86.

Accordingly, the Court concludes that even if intervening rights is not an element of prosecution laches, Novartis's conduct in prosecuting the '772 Patent does not trigger laches. Novartis's summary judgment of no prosecution laches is granted; Mylan's summary judgment of prosecution laches is denied.

B. Patent Misuse

"The doctrine of patent misuse is 'an extension of the equitable doctrine of unclean hands to the patent field.'" *Hoffman-LaRoche, Inc. v. Genpharm Inc.*, 50 F. Supp. 2d 367 (D.N.J. 1999) (quoting *U.S. Gypsum Co. v. Nat'l Gypsum Co.*, 352 U.S. 457, 465 (1957)). "The policy of the patent misuse doctrine is to prevent a patentee from using the patent to obtain market benefit beyond that which insures in the statutory patent right." *In re Gabapentin Patent Litig.*, 648 F. Supp. 2d 641, 652 (D.N.J. 2009) (citing *Monsanto Co. v. Scruggs*, 459 F.3d 1328, 1339 (Fed. Cir. 2006)). The Federal Circuit has held that to successfully assert the affirmative defense of patent misuse, the

alleged infringer must show that the patentee has impermissibly broadened the physical or temporal scope of the patent grant with anticompetitive effect." *Virginia Panel Corp. v. MAC Panel Co.*, 133 F.3d 860, 868 (Fed. Cir. 1997) (citation omitted).

Courts have recognized "certain specific practices as constituting *per se* patent misuse," *id.* at 869, "such as tying, enforced package licensing, price restraints, or extended royalty terms." *In re Gabapentin*, 648 F. Supp. 2d at 652 (citing *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1378 (Fed. Cir. 1998)). "Congress, however, has established that other specific practices may not support a finding of patent misuse." *Virginia Panel Corp.*, 133 F.3d at 869 (citing 35 U.S.C. § 271(d)(1994); *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 202 (1980) (construing earlier version of § 271(d))).

"When a practice alleged to constitute patent misuse is neither per se patent misuse nor specifically excluded from a misuse analysis by § 271(d), a court must determine if that practice is reasonably within the patent grant, *i.e.*, that it relates to subject matter within the scope of the patent claims." *M. Eagles Tool Warehouse, Inc. v. Fisher Tooling Co., Inc.*, No. 97-1568, 2007 U.S. Dist. LEXIS 23636, *20 (D.N.J. Mar. 30, 2007) (citing *Virginia Panel Corp.*, 133 F.3d at 869). If the practice relates to subject matter within the scope of the patent, "the practice does not have the effect of broadening the scope of the patent claims and thus cannot constitute patent misuse." *Virginia Panel Corp.*, 133 F.3d at 869 (citing *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700, 708 (Fed Cir. 1992)). However, if the practice extends the statutory rights of the patentee and "does so with anti-competitive effect, that practice must then be analyzed in accordance with the 'rule of reason.'" *Id.* (citing *Mallinckrodt, Inc.*, 976 F.2d at 708). Pursuant to the rule of reason "'the finder of fact must decide whether the questioned practice imposes an unreasonable restraint on competition,

taking into account a variety of factors, including specific information about the relevant business, its condition before and after the restraint was imposed, and the restraint's history, nature, and effect.'" *In re Gabapentin*, 648 F. Supp. 2d at 652 (quoting *Virginia Panel Corp.*, 133 F.3d at 869).

Mylan's arguments in support of its defense for patent misuse resemble those asserted in support of its prosecution laches defense. It contends that Novartis impermissibly broadened the temporal scope of its patent grant by abandoning the allowed fluvastatin claims in 1985 and refusing the examiner's entreaties to issue those previously allowed claims until Novartis received FDA approval to commercially market Lescol®. It further asserts that Novartis's abuse of the patent system extended the life of the '772 Patent from 2002 to 2011. Mylan posits that Novartis's extension of the allowed fluvastatin claims kept Mylan and other manufacturers from creating generic fluvastatin sodium, thereby extending Novartis's statutory rights and causing an anticompetitive effect. Mylan maintains that its patent misuse claim should be analyzed under the rule of reason.

Mylan relies on *In re Gabapentin* to support its assertion that courts have upheld patent misuse claims under similar circumstances – when patentees have argued that an underlying prosecution laches claim is "insufficient." However, the issue of patent misuse before the Court in *In re Gabapentin* occurred at the motion to strike stage, not at the summary judgment stage. 648 F. Supp. 2d at 642. The defendant in *In re Gabapentin* alleged that the plaintiff manipulated the prosecution of a patent "in a way that expanded the temporal scope of the patent with anticompetitive effect." *Id.* at 652. Plaintiff responded with an argument similar to the one advanced by Novartis – that "there is no authority for the proposition that prosecution delay can constitute patent misuse." *Id.* at 654. Plaintiff also argued that any delay in the issuance of the

patent at issue "resulted in nothing more than a shift in the beginning and end dates of the 17-year patent term rather than an expansion of its temporal scope." *Id.* at 653-54.

The *In re Gabapentin* Court disagreed with the plaintiff's assertion that it is not possible to unlawfully leverage a patent that had not yet issued, stating that such an argument "ignores cases in which patent applicants were found to have committed patent misuse by improperly leveraging pending patent applications." *Id.* at 655 (citing *Aronson v. Quick Point Pencil*, 440 U.S. 257, 265 (1979); *Boggild v. Kenner Prods.*, 776 F.2d 1315, 1320 (6th Cir. 1985)). The Court continued on to articulate that "[a]ny conduct that effectively extends the patentee's statutory rights with anticompetitive effect can qualify as misuse if the patentee sought to use the patent to secure more protection from competition than patent law intended to provide." *Id.* (citing *Blonder-Tongue Lab. Inc. v. Univ. of Illinois Found.*, 402 U.S. 313, 343 (1971); *Virginia Panel Corp.*, 133 F.3d at 869; *Smithkline Beecham Corp. v. Apotex Corp.*, 247 F. Supp. 2d 1011, 1046-47 (N.D. Ill. 2003)). Ultimately, the Court denied the motion to strike the patent misuse claim, explaining that "preserving a patent misuse defense at this stage of the litigation requires only allegations of conduct which has the effect of impermissibly extending the limited protection from competition afforded by the [] Patent." *Id.*

Because the analysis in *In re Gabapentin* occurred in the context of a motion to strike and not a motion for summary judgment, its decision is not binding on this instant motion. Further, based on the Court's independent review of the cases cited in *In re Gabapentin*, the Court is unwilling to conclude that Novartis's alleged delay prosecuting its patent impermissibly extended the temporal scope of the patent because the facts of the case at hand diverge from those in which patent misuse has been at issue. Both *Aronson* and *Boggild* involved allegations of misconduct in

the negotiation of licensing or royalty agreements that pertained to a patent or a pending patent application, not misconduct in the actual prosecution of the patent. *Aronson,* 440 U.S. at 264-65; *Boggild*, 776 F.2d at 1320-21; *see also Virginia Panel Corp.*, 133 F.3d at 868 (holding that alleged predatory practices of sending cease and desist letters, threatening to void warranties for failure to use components supplied by patentee, conditioning licenses on purchase of non-patented components, and threatening to sue government contractors for infringement "did not constitute patent misuse because they did not extend [the patent holder's] patent rights nor were they unreasonable competitive acts"). Those cases illustrate that the historical inquiry as to whether the temporal scope of the patent has been impermissibly broadened, focuses on whether the patent holder or patent applicant somehow used its patent or pending patent to elongate the time period in which the patent holder would benefit from its monopoly or to try to secure some type of exclusive benefit above and beyond that granted by the patent. No court has found impermissible expansion of the temporal scope of the patent where the length of the period of the patent monopoly remained the same, but the start of the period of the monopoly was postponed due to delays in the prosecution of the patent. There is no precedent to support a finding of impermissible broadening of the temporal scope of a patent due to delays in the prosecution of a patent.

In the absence of law to support Mylan's argument, this Court declines to expand the doctrine of patent misuse to the patent prosecution context. In the Court's view, the temporal scope of the patent was not extended by prosecution delays. The date on which Novartis obtained its patent is of no moment because Novartis's patent term is seventeen years and it would have been seventeen years even if the patent had issued in 1985. Therefore, the Court finds that the prosecution history of the '772 Patent has not impermissibly expanded the temporal scope of its patent. Because the Court has concluded as a matter of law that the temporal scope of the '772 Patent was not broadened,

the Court need not consider whether there was an anti-competitive effect or engage in a "rule of reason" analysis. Novartis's motion for summary judgment of no patent misuse is granted.

IV. CONCLUSION

For the reasons stated above, Novartis's summary judgment motion of no prosecution laches and no patent misuse is granted. Mylan's summary judgment motion on prosecution laches is denied. Novartis's '772 Patent is enforceable.

PETER G. SHERIDAN, U.S.D.J.

January 26, 2011